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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,658	10/22/2003	Stuart Weikel	8932-589-999	6494

51832 7590 01/09/2007  
JONES DAY  
222 EAST 41ST STREET  
NEW YORK, NY 10017-6702

EXAMINER
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PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/689,658

Applicant(s)

WEIKEL ET AL.

Examiner

Pedro Philogene

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al. (6,575,919) in view of Gelpcke (1,852,296).

With respect to claims 1 and 24, Reiley et al disclose a surgical instrument comprising a shaft (30) having longitudinal axis and proximal and distal ends having a length sufficient to create a percutaneous path to bone, a cross-section normal to the longitudinal axis, a tip (35) on the distal end of the shaft a plurality of facets that intersect to form a point for piercing tissue, at least two of the facets intersecting to form an edge for cutting tissue, and at least one other surface adjoining the cutting edge; as best seen in FIG.2, and as set forth in column 45, lines 3-11, wherein the cross section of the shaft varies along the length of the shaft, and a first cross-section of the first location along the length of the shaft has a first area and a second cross-section at a second location along the length of the shaft has a second area, the first area greater than the second area, and the second location is situated between the first location and the proximal end of the shaft; as best seen in FIG.1 and 9,11, since the tip is beveled.

It is noted that Reiley et al did not teach of a plurality of surfaces aligned with the longitudinal axis; as claimed by applicant. However, in a similar art, Gelpcke, evidences

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the use of a device, having a plurality of surfaces aligned with the longitudinal axis for preventing the shaft from turning inside a bore.

Therefore, given the teaching of Gelpcke, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Reiley et al, as taught by Gelpcke, to prevent the device from turning inside the sleeve.

With respect to claims 2-23, the above combination of references teaches all the limitations, as set forth; for example the polygonal cross-section, Gelpcke, line 51,, the cross section having similar shape, Gelpcke (FIG.2) or Reiley et al (FIGS.1,9,11), the planar surface of the facets (FIGS. 1,9) of Reiley et al or FIG.2 of Gelpcke the incline surfaces (FIG.2 ) of Gelpcke. The third cross section, as best seen near (7) in FIG.2 of Gelpcke, which is non-polygonal and having substantially a curve perimeter, since it is substantially circular; as best seen in FIG.2 of Gelpcke. The shaft having a handle attachment; as best seen in FIG.1 of Reiley et al, the handle is a lobe shape and is releasably secured to the handle attachment; the tip is asymmetrical and the shaft is symmetrical; as best seen in the FIGS., of Reiley et al.

### ***Response to Amendment***

Applicant's arguments filed 10/25/06 have been fully considered but they are not persuasive. Although applicant is arguing about a distal end located farthest from the surgeon, nowhere in claims 1 and 24 is applicant claiming a distal end . applicant is claiming two locations two cross-sections and two areas, the first area greater than the second area the second the second location situated between the first location and proximal end of the shaft. Reiley et al clearly disclose such surgical instrument

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comprising such shaft. The shaft of Reiley et al clearly having a first cross-section at a first location along the length of the shaft and a second second cross-section at a second location along the length of the shaft having a second area. The first area is considered to be closer to the handle and the secondt area is considered to be closer to the tip. And since the tip is beveled, the first area is greater than the tip area. Therefore, Reiley et al meet the limitations in claims 1 and 24.

In response to applicant's argument that Gelpcke is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the problem faced by Gelpcke is to make holes or cut with a shaft inside a holder. By providing a polygonally shaped shaft, Gelpcke was able to prevent the shaft from turning inside the holder while cutting. The problem faced by applicant is to make a hole or cut in tissue with a shaft inside a sleeve. By providing a polygonally shaped shaft, applicant was able to prevent the shaft from turning inside the sleeve. Therefore, the prior art is reasonably pertinent to the particular problem with which applicant was concerned.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

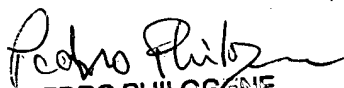
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pedro Philogene  
January 4, 2007

  
PEDRO PHILOGENE  
EXAMINER